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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/027,439	02/20/98	PORTUGAL	F 044198.0000

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EXAMINER

SOUAYA, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

19
09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 439
09/027,089

Applicant(s)

Portugal

Examiner

Jehanne Souaya

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1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above, claim(s) 21-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Currently, claims 37-39 are pending. The request filed on June 20, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/027,439 is acceptable and a CPA has been established. An action on the CPA follows. Any rejections not reiterated are hereby withdrawn. The following rejections are reiterated. They constitute the complete set being presently applied to the instant Application. This action is NON-FINAL.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilia et al or Hogan et al (US patent 5,714,321, 102(e) date is 2/24/94) in view of Faruque et al (J. Clinical Microbiology, 1992, vol. 30, pp 2996-2999).

The claims are drawn to nucleotide sequences of 10-40 nucleotides that comprise regions of the 16s ribosomal RNA or DNA sequences of Shigella species and E. Coli, wherein these sequences are capable of distinguishing Shigella from E.coli. Cilia et al teaches sequence heterogeneities among 16s RNA sequences of E. Coli and Shigella (see abstract, and figure 3) and teaches nucleotide differences among Eubacteria by showing a line up of regions from 16s genes

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across species levels, showing the nucleotide sequence similarities and differences. Hogan also teaches a method for preparing probes for use in qualitative and quantitative assays wherein the probes are capable of detecting and differentiating between eubacteria (see abstract). Hogan also teaches the hybridization of E. Coli probes to closely related organisms such as *Shigella boydii*, *Sh. flexneri*, *Sh. dysenteriae*, and *Sh. sonnei* (see col. 52, table 54). Faruque teaches studying restriction endonuclease restriction patterns of rRNA genes to distinguish between different strains of *Sh. Flexneri*. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct the DNA sequences of the claimed invention for the use of probes and primers that could distinguish *Shigella* from *E. Coli*. Methods of distinguishing between different eubacteria using probes and primers that target regions of similarity and differences was readily known in the art at the time of the invention and is exemplified by the Hogan patent. The ordinary artisan would have been motivated to construct probes and primers of the claimed invention to identify and differentiate *E.coli* from *Shigella* as Cilia teaches how closely related the two genus of bacteria are (see Fig 1) and Faruque teaches that closely related sequences from strains of the same bacteria can be used to differentiate the different strains. As the sequences of the 16s rRNA and rDNA sequences of the *shigella* species and *E.coli* sequences were known at the time of the invention, it would have been obvious for the ordinary artisan to construct probes and primers to regions of variability to be able to differentiate the closely related bacteria. Such methods were readily known in the art as is shown by the large amount of

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literature available in the art that identifies regions of variability among closely related bacteria for the purpose of constructing probes and primers useful in methods of differentiation.

4. No claims are allowable.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner

September 10, 2001

W. Gary Jones
W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600